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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,832

07/09/2003

Michael T. Carley

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7590

07/21/2009

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,832	<b>Applicant(s)</b> CARLEY ET AL.	
	<b>Examiner</b> JAMES L. SWIGER	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/1/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-8, 10-12 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan et al., "Logan" (US Patent 6,699,256) in view of Petersen et al. (US Patent 6,152,937).

Logan et al. disclose a method for manufacturing a clip comprising a step of providing material (see Col. 7, lines 35-45). It is noted that Logan discloses that what is provided to create the claimed clip/apparatus may be from a substantially cylindrical tube, particularly of nitinol. Tube-like structure for providing the material is not positively recited. The structure of the blank material may be more sheet-like. The 'sheet' would have a plane that defines the apparatus structure. Logan further discloses the step of removing portions (Col. 7, lines 37-39) leaving looped elements defining a periphery and tines extending from a flat plane. See fig. 2. The device is flattened to a two-dimensional configuration. Logan further discloses heat treating the clip with a planar configuration, as shown in Figs. 2 and 4.

The heating of the tube appears to be associated with the fingers (18/20), which are considered to be the "plurality of looped elements."

The tines may be biased to remain in the plane as shown in Fig. 34, 202), and the clip may further be deformed/compressed to a transverse configuration for loading onto a delivery apparatus and also loaded onto the apparatus (see fig. 16). The material provided may be a nickel-titanium alloy (Col. 7, lines 15-25). Logan discloses the claimed method except for specifically where the shape of the material provided is a sheet or where the loops are treated and programmed. The shape of the material provided is considered an obvious shape variant, and previously cited art to Peterson et al. (US Patent 6, 152, 937) further supports that a connector or clip may be formed from a sheet (Col. 5, lines 31-35) of similar material to Logan et al., such as nickel titanium alloy. Furthermore Petersen discloses that when treating the fingers (having the looped elements), they are able to retain their desired positions in use. Thus in treating them they are programmed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of the device of Logan et al. having at least the step of providing a sheet of material in view of Peterson et al. '937 for improved cutting/edging of the tines and for programming them in a desired way into respective annular structures.

Claims 3-4, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan et al. '256 in view of Petersen and in further view of Abrams et al. (US Patent 6,036,720). Logan in view of Peterson disclose the claimed invention except for a therapeutic coating or a radiopaque coating on at least a portion of the clip. Abrams et al. disclose a radiopaque marker (Col. 7, lines 24-35) so that it may be visible during a fluoroscopy procedure, and also at least a therapeutic coating, such as a

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polymeric material (Col. 7, lines 30-35) that allow the device to be easier to work with and be more acceptable to the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Logan in view of Petersen having at least a therapeutic coating or radioactive marker in view of Abrams et al. to better use and maneuver the, as the therapeutic coating may make it more acceptable by the body, and the radiopaque coating will allow better viewing under fluoroscopic visualization.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Logan in view of Petersen and in further view of Salahieh et al. (US Patent 5,769,870). Logan in view of Petersen disclose the claimed invention except for the device having at least a coating of a hydrophilic polymer. Salahieh et al. teach the use of a hydrophilic polymer that can expand in the presence of an aqueous fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Logan in view of Petersen having at least a hydrophilic polymer in view of Abrams et al. to better use the device during surgery to prevent leakage of fluid and to fill the surgical site area.

### ***Response to Arguments***

Applicant's arguments submitted 3/16/2009 with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection. It is held that when programming part of the clip to a desired configuration, the plurality of looped elements in the clip are considered substantially part of the fingered elements.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775